

Creapure® - product quality and safety information

Creapure® (creatine monohydrate, CAS-No. 6020-87-7) is manufactured by chemical synthesis using solely synthetic raw materials and water as solvent. No materials of plant or animal origin are applied or used during production. The manufacturing site is Trostberg, Germany.

For Creapure® all relevant requirements of regulation (EC) No 178/2002 are fulfilled during manufacturing and distribution of our product. Within the scope of recommended application Creapure® is deemed to be safe for human consumption.

Creapure® is produced according to regulation (EC) No 852/2004 (hygiene on foodstuff) and according to 21 CFR 111 (cGMP in manufacturing, packaging, labeling, or holding operations of dietary supplements). For production of Creapure® a HACCP system following Codex Alimentarius was implemented and we hold an HACCP certificate for the production. The certificate is available on special request.

Product properties	Declaration
Kosher	Creapure® is in line with Kosher regulations. On special request a Kosher certificate can be made available.
Halal	Creapure® is in line with Halal regulations. On special request a Halal certificate can be made available.
Vegetarian/vegan	Creapure® is suitable for vegetarians and vegans.
Allergens	Creapure® does not contain or come in contact with ingredients as listed in Annex II of regulation (EU) No 1169/2011.
GMO	Creapure® and the raw materials used do not contain, consist of or are produced from GMO as defined in regulation (EC) No 1829/2003, and they do not contain ingredients produced from GMO. Therefore, our product does not need labelling according to regulation (EC) No 1829/2003 and 1830/2003.
TSE/BSE	Creapure® is manufactured by chemical synthesis using solely synthetic raw materials and water as solvent. No materials of plant or animal origin are applied/used during

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Product properties	Declaration
	production. Therefore Creapure® does not fall within the scope of regulation (EC) No 999/2001 and its amendments.
Nanomaterials	Creapure® does not fall within the scope of the definition of nanomaterials as given in Commission Recommendation 2011/696 and does not need labelling according to regulation (EC) No 1169/2011.
Solvents	During production only water is used as solvent, hence Creapure® is compliant with directive 2009/32/EC.
Contaminants	<p>Creapure® fulfills requirements for maximum contents of heavy metals in dietary supplements as given in the annex, section 3 of regulation (EC) No 1881/2006 and its relevant amendments, namely regulations No 629/2008, No 488/2014 and 2015/1005.</p> <p>During production no dioxins and PAHs are intentionally introduced or formed.</p>
Pesticides	Due to the synthetic origin of Creapure® our product does not fall within the scope of regulation (EC) No 396/2005.
Ionizing radiation	Creapure® is not subject to ionizing radiation.
WADA Prohibited List	During production and handling of Creapure® no substances as listed on the WADA Prohibited List 2017 and 2018 are intentionally introduced into the product.
Packaging	The bags used for packaging of Creapure® comply with regulation (EC) No 1935/2004.

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Legal status EU

According to Directive 2002/46/EC (article 2(a)) and the German NemV (§ 1 (1), no. 2) Creapure® belongs to the class of other substances with a nutritional or physiological effect, and as such is a permissible ingredient in food supplements. Similarly, under regulation (EC) 1925/2006 (article 1, (1) and article 2, 2.) Creapure® may be added to food.

Directive 2002/46 translates into national law, and so far, only some countries of the EU developed an annex listing permissible ingredients within the class of other substances with a nutritional or physiological effect. Moreover, no such harmonized list exists within regulation (EC) 1925/2006.

Creapure® can be advertised with two approved health claims in Europe.

Claim type	Claim	Conditions of use	Commission regulation
Art. 13(1)	Creatine increases physical performance in successive bursts of short-term, high intensity exercise.	<p>The claim may be used only for food which provides a daily intake of 3 g of creatine. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of creatine.</p> <p>The claim may be used only for foods targeting adults performing high intensity exercise.</p>	<p>(EC) 432/2012 of 16/05/2012</p> <p>Online source: http://data.europa.eu/eli/reg/2012/432/oj</p>
Art. 13(5)	Daily creatine consumption can enhance the effect of resistance training on muscle strength in adults over the age of 55.	Information shall be provided to the consumer that: the claim is targeting adults over the age of 55, who are engaged in regular resistance training, the beneficial effect is obtained with a daily intake of 3 g of creatine in conjunction with resistance training, which allows an increase in the workload over time and which should be performed at least three times per week for several weeks, at an intensity of at least 65 % -	<p>(EC) 2017/672 of 07/04/2017</p> <p>Online source: http://data.europa.eu/eli/reg_impl/2017/672/oj</p>

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Claim type	Claim	Conditions of use	Commission regulation
		<p>75 % of one repetition maximum load*. The claim may be used only for food targeting adults over the age of 55, who are engaged in regular resistance training.</p> <p>*Repetition maximum load is the maximum weight or force an individual can exert in a single lift.</p>	

The wording of the respective health claims in all official languages of the EU can be accessed via the links as given in the above table.

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